PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

Wednesday, January 15, 2003

9:30 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair ROBERT D. REISCHAUER, Ph.D., Vice Chair SHEILA D. BURKE AUTRY O.V. "PETE" DeBUSK NANCY ANN DePARLE DAVID DURENBERGER ALLEN FEEZOR RALPH W. MULLER ALAN R. NELSON, M.D. JOSEPH P. NEWHOUSE, Ph.D. CAROL RAPHAEL ALICE ROSENBLATT JOHN W. ROWE, M.D. DAVID A. SMITH RAY A. STOWERS, D.O. MARY K. WAKEFIELD, Ph.D. NICHOLAS J. WOLTER, M.D.

<u>AGENDA ITEM:</u> Paying for new technologies -- Chantal Worzala

MR. HACKBARTH: As I recall from reading the material, Chantal, there is, with maybe one exception, not a whole lot that's different from our previous discussions of this topic. But in the terms of the information presented, the substance of it, it should be familiar stuff to the commissioners at this point, so I'd ask that you move through it quickly, and then we do have some recommendations to deal with.

DR. WORZALA: Sure. The draft chapter is in Tab E. Also in that tab is a draft of an appendix on Medicare's coverage process. We're not presenting any of the coverage material but if you have any feedback on it we certainly welcome that.

This is the outline of the chapter of these four areas. I'll discuss the first three. The last one I won't be discussing. We've discussed it previously. If you have any comments on it, please feel free to bring them up at this point.

This slide shows the basic argument of how prospective payment deals with new technology as a standard system. It's felt that since there is a fixed payment for a bundled service, there is an incentive to use cost-decreasing technology but not cost-increasing new technologies. There's a sense that the process of revising the classification systems and recalibrating the relative weights is a time-consuming process. This is of necessity due to the multiple actors involved and public comment. But it does seem to slow down incorporation of new technology and that argument has led to the implementation of new technology payment mechanisms in both the inpatient and outpatient PPSs.

This next slide shows the four new technology payment mechanisms that are discussed in the paper across four dimensions. These are the criteria used by CMS to determine which technologies will be paid, the way the payments are financed, the unit of payment, and how the payment amount is set. I had planned to walk you through a couple of the ways in which these payment mechanisms vary, but in the interest of time I think I will stick with just the one thing that is the subject of a recommendation and that is the eligibility criteria.

The eligibility criteria are a key means for ensuring that additional payments are well targeted. Most observers agree that additional payments should be reserved for technologies that are truly new, costly and have a clear clinical benefit. When considering applications for the inpatient add-on payments and the outpatient pass-through payments for medical devices, CMS applies newness, cost, and clinical benefit criteria.

However, for pass-through drugs and biologicals under the outpatient PPS, CMS applies only newness and cost criteria. This leads to an inconsistency in the treatment of a drug or biological across the two payment systems as well as an inconsistency across types of technology within the outpatient pass-through payment mechanism.

This slide shows the clinical criteria for the inpatient add-on payments and medical devices under the outpatient pass-throughs. To be eligible, a new technology must substantially improve relative to technologies previously available, the diagnosis or treatment of beneficiaries. CMS has provided examples of how these criteria might be met. They're listed on this slide and we did discuss them in December.

It's important to remember that the eligibility here is for additional payment, certainly not for coverage. Physicians are free to use a given technology whether or not it is eligible for additional payment, and there will be the base APC payment for a technology regardless of its

pass-through eligibility status. So what we're really talking about here is applying clinical criteria when determining that a technology is eligible for additional payment beyond the base APC rate.

To address the inconsistent eligibility criteria, staff proposed the following recommendation for your consideration. The Secretary should introduce clinical criteria for eligibility of drugs and biologicals to receive pass-through payments under the outpatient PPS. This recommendation should have no impact on spending since the pass-through payments are implemented in a budget neutral fashion.

I'll stop there.

MR. HACKBARTH: Thank you. Any questions or comments? Are we ready to vote on the recommendation? All in favor of the recommendation? Opposed?

Abstain?

Thank you, Chantal.